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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,859	08/16/2000	Leonard S. Girsh	5163*3	2441

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	19

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/639,859	GIRSH, LEONARD S.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,15-18,23-39,45-79 and 84-100* is/are pending in the application.

4a) Of the above claim(s) *1,3-11,15-18,23-39 and 84-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-79 and 89-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-11, 15-18, 23-39, 45-79 and 84-100 are pending.

Applicants' amendments filed March 11, 2003 (Paper No. 17) and April 11, 2003 (Paper No. 18) are acknowledged, and applicants' response has been fully considered. Claims 80-83 and 40-44 have been cancelled, claims 47, 48, 51, 58, 60, 71, 73-79 and 89 have been amended, and new claims 96-100 have been added. Claim 1, 3-11, 15-18, 23-39 and 84-88 are non-elected inventions and remain withdrawn from consideration, thus, claims 45-79 and 89-100 are examined.

2. A formal drawing for Fig. 1 filed March 11, 2003 is acknowledged.

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 47, 48, 51, 52, 58, 60, 66, 67, 69-71, 73-77 and 80 under 35 U.S.C.112, second paragraph, regarding the term "derived from", "and/or", "L-glycine", "any combination of (a) through (j)", is withdrawn in view of applicants' cancellation of the claim, applicants' amendment of the claim, and applicants' response at page 5 in Paper No. 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 45-79 and 89-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a therapeutic composition, comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically

pure essential L-amino acid, where the identities and the amounts of each component in the composition are defined as indicated in the prior art, does not reasonably provide enablement for a therapeutic composition or anti-inflammatory medicament comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically pure essential L-amino acid, where the amounts and identities of the extracellular matrix compound, the lipid, and the amino acid are not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 45-79 and 89-100 are directed to a therapeutic composition or anti-inflammatory medicament comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically pure essential L-amino acid. The specification, however, only discloses cursory conclusions (page 8) without data supporting the findings, which state that the invention relates to a composition and uses thereof for treatment of damaged tissue comprising at least one essential L-amino acid and at least one essential lipid, wherein the composition is administered to a mammal suffering from severe tissue damage; or wherein the molar ratio of amino acids corresponds to the molar ratio of amino components in a mammalian tissue protein or to the molar ratio of amino components in a medicament such as cycolsporin or penicillin. There are no indicia that the present application enables the full scope in view of the composition comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically pure essential L-amino acid as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue

experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding the identities and the amounts of components in the composition, and the effects of the composition in treating damaged tissue or diseases, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the claimed variants in the composition. The specification has not shown the compostion contains all three components with specific amount of each component, most examples indicate the composition contains L-amino acid, essential fatty acids (e.g., linolenic acid and EPA) and phospholipid (see Cases 1-11).

(3). The state of the prior art and relative skill of those in the art:

The prior art indicates a composition for treating nails or reactivating the physiological growth of hair, comprising a glycoprotein, an L-amino acid, and a phospholipid (Garson *et al.*, U. S. Patent 5,753,211; Montanari *et al.*, U. S. Patent 6,479,059). However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the identities and the amounts of each

component in the composition, and the effect of the composition in treating damaged tissue to be considered enabling for the claimed variant.

(4). Predictability or unpredictability of the art:

The specification has shown the effect of the composition containing L-amino acid, essential fatty acids (e.g., linolenic acid and EPA) and phospholipid (see Cases 1-11). However, the specification has not demonstrated the effect of a composition containing all three components with defined amounts, the invention is highly unpredictable regarding the effect of the composition in the treatment of damaged tissue.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a therapeutic composition or anti-inflammatory medicament comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically pure essential L-amino acid. The specification indicates a composition comprising at least one essential L-amino acid and at least one essential lipid can be used for treating tissue damage; or a composition comprising mixtures of L-amino acids and at least one essential lipid, wherein the molar ratio of amino acids corresponds to the molar ratio of amino components in a mammalian tissue protein or to the molar ratio of amino components in a medicament such as cycolsporin or penicillin (page 8). However, the specification has not demonstrated the compostion contains all three components with specific amount of each component, nor has shown the effects of the composition in the treatment of damaged tissue or diseases. There is no working example demonstrating the effect of the composition containing all three components, most examples indicate the composition contains L-amino acid, essential

fatty acids (e.g., linolenic acid and EPA) and phospholipid, and the effect of these compositions (see Cases 1-11). Since the specification fails to provide sufficient teachings on the use and effect of the composition containing all three components, it is necessary to carry out further experimentation to assess the effects of the compositions.

(6). Nature of the Invention

The scope of the claims encompasses a therapeutic composition or anti-inflammatory medicament comprising at least one extracellular matrix compound, at least one polar surface active lipid, and at least one optically pure essential L-amino acid, but the specification does not demonstrate the use and the effect of the composition. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the art is unpredictable regarding the effects of claimed composition, and the guidance and the teaching in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of the composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 56-64, 72, 73, 75, 77-79, 89-95, 97 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 56, 57 and 61-64 are indefinite because of the use of the term "said aliphatic amino acids contain short chain fatty acids", "said amino acids contain ammoniated short chain fatty acids at the alpha carbon position", or "said amino acid contains butyric acid as the short chain fatty acid". The term cited renders the claim indefinite, it is unclear how a short chain fatty acid is attached to the aliphatic amino acid, and what are the structures for these amino acids. Claims 57 and 61-64 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

7. Claim 58 recites the limitation "glycine" in line 2. There is insufficient antecedent basis for this limitation in the claim because the independent claim, claim 45 recites optically pure L-amino acids, while glycine is not optically active L-amino acid. Claims 59, 60, 72, 73, 75, 77 and 79 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend. See also claim 97.

8. Claims 78-79 are indefinite because of the use of the term "biochemical components that pharamcodynamically aid in reorganization, regrowth, and regeneration of normal tissue or disease tissue". The term cited renders the claim indefinite, it is unclear what compounds are as to "the biochemical components", and how these components aid in reorganization, regrowth and regeneration of normal tissue or disease tissue.

In response, applicants indicate the claim has been amended to remove reference to "biochemically key" and "continue bonding effects" (page 5 of the response). The argument is not found persuasive because the claim does not identify the biochemical components as indicated above.

9. Claim 89, for example, is indefinite because of the use of the term "amino acid ratios found in healthy or normal peptides, polypeptides, proteins, medicants or tissues". The term "amino acid ratios found in healthy or normal peptides, polypeptides, proteins, medicants or tissues" renders the claim indefinite, it is unclear what are the ratios of the amino acid components in healthy or normal peptides, polypeptides, proteins, medicants or tissues because the peptides, polypeptides, proteins, medicants or tissues are not identified. See also claims 90-95. The word "medicants" is misspelled.

In response, applicants indicate the claim has been amended to define the peptides, polypeptides, proteins, medicaments or tissues more clearly (pages 5-6 of the response). The argument is not persuasive because the claim does not identify the healthy or normal peptides, polypeptides, proteins, medicaments or tissues as indicated above.

10. Claim 97 is indefinite because of the use of the term "L-gamma amino butyric acid". The term "L-gamma amino butyric acid" renders the claim indefinite, it is unclear how gamma-amino butyric acid is optically active because the compound does not have a chiral center. See also claim 99.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 45-54, 68, 69 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Garson *et al.* (U. S. Patent 5,753,211).

Garson *et al.* teach a composition for treating nails comprising collagen, cystine, phospholipids, vitamins and other active agents (column 3, lines 17-26; claims 45, 53, 54, 68, 69 and 74), and it is known that collagen, cystine, phospholipids and vitamins can be synthetically produced or isolated from cellular or tissue sources (claims 46-52).

In response, applicants indicate the 211' patent does not teach "optically pure L-cystine", the designation of cystine is indicative of a racemic mixture of cystine as opposed to an optically pure enantiomer L-cystine or D-cystine (page 6 of the response). The argument is not found persuasive because cystine can be an L-enantiomer or a racemic mixture of D and L-enantiomers, which meets the criteria of claim 45 since the claim recites the term "comprising" for the components in the composition. Furthermore, L-amino acid such as L-cystine is a naturally occurring amino acid and is usually indicated as cystine without the designation of "L", thus cystine is either L-enantiomer or D,L-racemic mixture.

12. Claims 45-54, 58, 68, 69, 74 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Montanari *et al.* (U. S. Patent 6,479,059, priority date, June 21, 1999).

Montanari *et al.* teach a composition for reactivating the physiological growth of hair comprising a glycoprotein, cysteine, lysine, a phospholipid and zinc (column 2, lines 17-60; column 4, lines 10-63; Examples 1 and 2; claims 45, 53, 54, 68, 69, 74 and 97), and it is known that glycoprotein, cysteine, lysine, and phospholipid can be synthetically produced or isolated from cellular or tissue sources (claims 46-52).

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

christopher S. Low

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June 26, 2003